REMARKS

Favorable reconsideration of this application in light of the following elections remarks is respectfully requested.

No claims having been canceled or added, the Applicants respectfully submit that claims 1-28 remain pending in this application.

The Applicants submit that the amendments to claims 18 and 20 are intended only to improve clarity and provide appropriate antecedent bases and do not, therefore, constitute the introduction of any new matter.

Restriction Requirement

The Examiner is requiring restriction of one of the following inventions:

I. Claims 1-5, 8-13, 16, 26 and 27, drawn to a drug as set forth in claim 1 wherein an antibody displayed on a particle surface fused with the particle forming protein via ZZ tag or biotin-streptavidin interaction and wherein the particle forming protein comprises a modified hepatitis B surface-antigen protein;

II. Claims 6, 7 and 25, drawn to a drug set forth in claim 1 wherein the hollow nanoparticles of particle forming protein are expressed in a eukaryotic cell;

III. Claims 14 and 15, drawn to a drug set forth in claim 1 wherein the disease treating substance comprises a gene;

IV. Claims 18-21, drawn to hollow nanoparticles that comprise a hepatitis B virus surface-antigen;

V. Claims 22-24, drawn to a drug set forth in claim 2 wherein an **cancer specific antibody** displayed on a particle surface fused with the particle forming protein via ZZ tag or biotin-streptavidin interaction;

VI. Claims 22-24, drawn to a drug set forth in claim 2 wherein an **anti-virus protein antibody** displayed on a particle surface fused with the particle forming protein via ZZ tag or biotin-streptavidin interaction;

VII. Claim 17, drawn to a disease treating method administering the drug of claim 1; and

VIII. Claim 28, drawn to a disease treating method administering the drug of claim 2.

Applicants' Election

In response to the Examiner's restriction requirement, Action at 2, the Applicants elect, with traverse, the claims of Group I, specifically claims 1-5, 8-13, 16, 26 and 27, drawn to a drug as set forth in claim 1 wherein an antibody displayed on a particle surface fused with the particle forming protein via ZZ tag or biotin-streptavidin interaction and wherein the particle forming protein comprises a modified hepatitis B surface-antigen protein for prosecution in this application. The Applicants specifically reserve the right to file one or more divisional applications directed to non-elected inventions.

Argument in Support of Traversal

The Applicants contend that the technical feature identified for the Group IV claims is distinct from the Kuroda reference in that each of the claimed hepatitis B virus surface-antigen proteins recited in claims 18-21 incorporate modifications in the pre-S region that improve their utility in parts of the body other than the liver. Specification at 5-6. Accordingly, the Group IV

claims do represent a contribution over the prior art and do not, therefore, lack unity of invention according to PCT Rule 13.2.

For all of the above stated reasons, reconsideration and withdrawal of the pending restriction requirement and favorable action on the elected claims in the instant application are earnestly solicited by the Applicants.

Species Election

The Examiner is also requiring an election of species between the disclosed species of antibody for prosecution on the merits. Currently, claims 1-5 and 22-24 are deemed generic with respect to this election.

The Examiner is also requiring an election of species between disclosed species of particle forming proteins. Currently, claims 1, 8-13 and 18-21 are deemed generic with respect to this species election.

The Examiner is also requiring an election of species between disclosed species of encapsulated substances. Currently claim 1 is deemed generic with respect to this species election.

Applicants' Species Election

With respect to the disclosed species of antibody, the Applicants elect, with traverse, the "cancer-specific antibody" as recited in claim 2 for prosecution on the merits. The Applicants submit that claims 1-5 and 22-24 remain generic with respect to this election.

With respect to the disclosed species of particle forming proteins, the Applicants elect, with traverse, the "modified hepatitis B virus surface-antigen protein" as recited in claim 8. The Applicants submit that claims 1-13 and 18-21 are generic with respect to this species election.

With respect to the disclosed species of encapsulated substances, the Applicants elect, with traverse, the "thymidine kinase (KSV1tk) gene derived from simple herpes virus" as recited in claim 15. The Applicants submit that at least claims 1 and 14 are generic with respect to this species election.

Arguments in Support of Traverse

The Applicants note that the simple recitation of "independent and distinct" is not sufficient to warrant a species election where the members of the group disclosed in the specification possess at least one property in common for which they are utilized in the claimed composition. MPEP § 803.02. In this instance, each of the identified of species are grouped be a common ability, specifically the ability to form nanoparticles, comprise an antibody or comprise substance that will disrupt the function of the targeted cells respectively.

The Applicants further note that with respect to nucleotide sequences, MPEP § 803.04, although recognizing that nucleotide sequences are usually deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. § 121, provides that:

> to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided *sua sponte* to partially waive the requirements of 37 CFR § 1.141 *et seq.* and permit a ***reasonable number*** of such nucleotide sequences to be claimed in a single application. It has been determined that normally ***ten sequences constitute a reasonable number for examination purposes***. Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application ***without restriction***. In addition to the specifically selected sequences, those sequences which are patentably indistinct from the selected sequences will also be examined. Furthermore, nucleotide sequences encoding the same protein

> are not considered to be independent and distinct inventions and will continue to be examined together.

MPEP § 803.04 (emphasis added.)

Accordingly, the Applicants maintain that proteins, whether constituting the particle-forming, antibody or encapsulated "substance" portions of the recited drug should not be subjected to any more stringent restriction/election requirements. The Applicants contend, therefore, that the present species election to the extent it purports to force an election of a single protein or sequence ID should be withdrawn and that Applicants should be allowed to select at least 10 sequences for examination in this application.

The Applicants also note that conventional restriction practice allows for examination of a "reasonable" number of independent or distinct inventions and/or species in a single application. In light of recent office actions, it appears that certain groups within the USPTO have taken it upon themselves to decide that the only reasonable number is "1," thereby essentially eliminating traditional Markush practice. Unless and until the Applicants are provided with or directed to some statutory or regulatory support for this new definition of "reasonable number," the Applicants submit that the application of such a definition is arbitrary and improper. Accordingly, absent identification of some appropriate basis for these new practices, the Applicants submit that the identified species should be regrouped in some logical fashion to provide groups of a "reasonable number" of species for examination in this application.

Finally, the Applicants note that MPEP § 803 provides that where the search and examination of all the claims in an application can be made without "serious burden," the examiner ***must*** examine the claims on the merits, even if they include claims to independent or distinct inventions. The Applicants note that the automated searching tools, in conjunction with the provision of the disclosed amino acid and nucleotide sequences in CRF tends to remove any "serious burden" with regard to the searching and examination inventions involving sequence

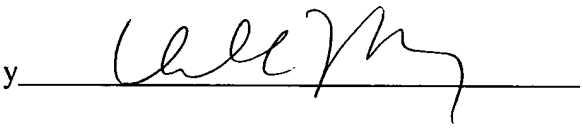
listings. Accordingly, the Applicants request that the Restriction and Election requirements imposed in the Action be reconsidered and withdrawn or materially modified in compliance with the provisions of the MPEP.

For all of the above stated reasons, reconsideration and withdrawal of the pending species election requirements and favorable action on the elected claims in the instant application are earnestly solicited by the Applicants.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 08-0750 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

HARNESS, DICKEY & PIERCE, PLC

By 

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